



DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 88

[NIOSH Docket 094]

World Trade Center Health Program; Petition 013--Autoimmune Disease; Finding of Insufficient Evidence

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Denial of petition for addition of a health condition.

SUMMARY: On April 4, 2016, the Administrator of the World Trade Center (WTC) Health Program received a petition (Petition 013) to add "relapsing remitting multiple sclerosis (autoimmune)" to the List of WTC-Related Health Conditions (List). Upon reviewing the information provided by the petitioner, the Administrator has determined that Petition 013 is not substantially different from Petitions 007, 008, 009, and 011, which also requested the addition of autoimmune diseases, including various subtypes. The Administrator recently published responses to the four previous petitions in the **Federal Register** and has determined that Petition 013 does not provide additional

evidence of a causal relationship between 9/11 exposures and autoimmune diseases, including multiple sclerosis. Accordingly, the Administrator finds that insufficient evidence exists to request a recommendation of the WTC Health Program Scientific/Technical Advisory Committee (STAC), to publish a proposed rule, or to publish a determination not to publish a proposed rule.

DATES: The Administrator of the WTC Health Program is denying this petition for the addition of a health condition as of [INSERT DATE OF PUBLICATION IN **FEDERAL REGISTER**].

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A. WTC Health Program Statutory Authority

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111-347, as amended by Pub. L. 114-113), added Title XXXIII to the Public Health Service Act (PHS Act),¹ establishing the WTC Health Program within the Department of Health and Human Services (HHS). The WTC Health Program provides medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001 or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

All references to the Administrator of the WTC Health Program (Administrator) in this notice mean the Director of

¹ Title XXXIII of the PHS Act is codified at 42 U.S.C. 300mm to 300mm-61. Those portions of the Zadroga Act found in Titles II and III of Public Law 111-347 do not pertain to the WTC Health Program and are codified elsewhere.

the National Institute for Occupational Safety and Health (NIOSH) or his or her designee.

Pursuant to section 3312(a)(6)(B) of the PHS Act, interested parties may petition the Administrator to add a health condition to the List in 42 CFR 88.1. Within 90 days after receipt of a petition to add a condition to the List, the Administrator must take one of the following four actions described in section 3312(a)(6)(B) and 42 CFR 88.17: (1) Request a recommendation of the STAC; (2) publish a proposed rule in the **Federal Register** to add such health condition; (3) publish in the **Federal Register** the Administrator's determination not to publish such a proposed rule and the basis for such determination; or (4) publish in the **Federal Register** a determination that insufficient evidence exists to take action under (1) through (3) above. However, in accordance with 42 CFR 88.17(a)(4), the Administrator is required to consider a new petition for a previously-evaluated health condition determined not to qualify for addition to the List only if the new petition presents a new medical basis -- evidence not previously reviewed by the Administrator -- for the association between 9/11 exposures and the condition to be added.

B. Approval to Submit Document to the Office of the Federal Register

The Secretary, HHS, or her designee, the Director, Centers for Disease Control and Prevention (CDC) and Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), authorized the undersigned, the Administrator of the WTC Health Program, to sign and submit the document to the Office of the Federal Register for publication as an official document of the WTC Health Program. Thomas R. Frieden, M.D., M.P.H., Director, CDC, and Administrator, ATSDR, approved this document for publication on August 24, 2016.

C. Petition 013

On April 4, 2016, the Administrator received a petition from a responder in the WTC Health Program to add "relapsing remitting multiple sclerosis (autoimmune)" to the List (Petition 013).² Because the petitioner identified the requested health condition as "the autoimmune disease of multiple sclerosis" in the petition narrative and used a study of autoimmune diseases among WTC responders to

² See Petition 013, WTC Health Program: Petitions Received, <http://www.cdc.gov/wtc/received.html>.

provide the medical basis for the petition,³ the Administrator determined that the petitioned health condition is "autoimmune diseases, including multiple sclerosis."

This is the fifth petition to the Administrator requesting the addition of autoimmune diseases, including various subtypes, to the List; each of the first four autoimmune disease petitions were denied due to insufficient evidence, as described in respective **Federal Register** notices (FRNs).⁴ The medical basis for a potential addition to the List may be demonstrated by reference to a peer-reviewed, published, epidemiologic study about the health condition among 9/11-exposed populations or to clinical case reports of health conditions in WTC responders or survivors.⁵ In accordance with WTC Health Program policy, the Science Team reviews references for relevance, and relevant studies are further reviewed for

³ Id.

⁴ "World Trade Center Health Program; Petition 007-Autoimmune Diseases; Finding of Insufficient Evidence," 80 FR 32333 (June 8, 2015); "World Trade Center Health Program; Petition 008-Autoimmune Diseases; Finding of Insufficient Evidence," 80 FR 39720 (July 10, 2015); "World Trade Center Health Program; Petition 009-Autoimmune Diseases; Finding of Insufficient Evidence," 80 FR 65980 (Oct. 28, 2015); and "World Trade Center Health Program; Petition 011-Autoimmune Diseases; Finding of Insufficient Evidence," 81 FR 24047 (April 25, 2016).

⁵ See John Howard, Administrator of the WTC Health Program, Policy and Procedures for Handling Submissions and Petitions to Add a Health Condition to the List of WTC-Related Health Conditions, May 14, 2014, <http://www.cdc.gov/wtc/pdfs/WTCHPPPPetitionHandlingProcedures14May2014.pdf>.

quality and quantity.⁶ The current petition, Petition 013, presented five references to support the request to add “relapsing remitting multiple sclerosis (autoimmune)” to the List.

Petition 013 references 1, 2, and 4 are links to the same newspaper article announcing the online publication of a study published in 2015.⁷ Petition 013 reference 3 is a different newspaper article announcing the online publication of the same study.⁸ These four references identify a 2015 study by Webber et al., a peer-reviewed, published epidemiologic study of autoimmune diseases among 9/11-exposed responders and survivors, titled “Nested Case-Control Study of Selected Systemic Autoimmune Diseases in World Trade Center Rescue/Recovery Workers.”⁹ The 2015 Webber et al. study has already been evaluated by the

⁶ Information is determined to be relevant if it is presented in peer-reviewed, published, epidemiologic studies of the health condition in 9/11-exposed populations. John Howard, Administrator of the WTC Health Program, Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions, May 11, 2016, http://www.cdc.gov/wtc/pdfs/WTCHP_PP_Adding_NonCancer_Conditions_Revision_11_May_2016.pdf

⁷ The article, by Amy Norton, is published in reference 1, New Health Worry for 9/11 Recovery Workers, HealthDay, March 19, 2015, in www.cbsnews.com/news/ground-zero-workers-at-risk-of-autoimmune-diseases; reference 2, 'Ground Zero' Workers at Risk of Autoimmune Diseases: Study, HealthDay, March 19, 2015, in <http://www.medicinenet.com/script/main/art.asp?articlekey=187534>; and reference 4, 'Ground Zero' Workers at Risk of Autoimmune Diseases: Study, HealthDay, March 19, 2015, <https://consumer.healthday.com/senior-citizen-information-31/misc-arthritis-news-41/ground-zero-workers-at-risk-of-autoimmune-diseases-study-697581.html>. The study announced in the Norton article is the 2015 study by Webber et al., cited *infra* note 9.

⁸ Nancy Walsh, Autoimmunity Rising in 9/11 Workers, MedPage Today, March 19, 2015, <http://www.medpagetoday.com/Rheumatology/GeneralRheumatology/50548>.

⁹ Mayris Webber, William Moir, Rachel Zeig-Owens, et al., Nested Case-Control Study of Selected Systemic Autoimmune Diseases in World Trade Center Rescue/Recovery Workers, *Arthritis Rheumatol* 2015;67(5):1369-1376.

Administrator in consideration of the other four autoimmune disease petitions, and is discussed below.

The fifth reference provided in Petition 013 does not specifically identify a peer-reviewed, published epidemiologic study of the health condition among 9/11-exposed populations, nor is it a clinical case report of the health condition in WTC responders or survivors. Petition 013 reference 5 is a link to the proceedings of a research meeting conducted by the WTC Health Program in 2014.¹⁰ Two abstracts found in the proceedings address the topic of autoimmune disease among the 9/11 population -- "Autoimmune Disease among WTCHR [World Trade Center Health Registry] Registrants: Survey Design and Preliminary Response Rates," and "Post-9/11 Incidence of Systemic Autoimmune Diseases in the FDNY Cohort." The former abstract references an unpublished study; because unpublished studies do not meet the Program's standard for relevance, it was not further considered. The latter abstract describes a study that resulted in the 2015 Webber et al. publication discussed in this action and reviewed in full in the April 2016 FRN for Petition 011.

¹⁰ WTC Health Program, Research Meeting Proceedings, June 17-18, 2014, www.cdc.gov/wtc/proceedings.html.

As discussed in the April 2016 FRN finding of insufficient evidence for Petition 011, the 2015 Webber et al. study looked at the association between 9/11-related exposures and systemic autoimmune diseases. It was found to be a published, peer-reviewed epidemiologic study of autoimmune diseases in the 9/11 population, and therefore deemed relevant. However, the study was found to exhibit substantial limitations, and it was ultimately concluded not to have the potential to form the basis for a decision on whether to propose adding autoimmune diseases to the List of WTC-Related Health Conditions.¹¹

In addition to a review of the studies presented in Petition 013, the WTC Health Program Science Team conducted a review of the scientific literature to determine if the available scientific information has the potential to provide a basis for a decision on whether to add the condition to the List. A previously conducted literature review for autoimmune diseases in response to Petition 007¹² included all of the autoimmune conditions in the 2015 Webber et al. study.¹³ In reviewing Petition 013, the

¹¹ 81 FR 24047 at 24049.

¹² See 80 FR 32333 at 32334.

¹³ Rheumatoid arthritis; spondyloarthritis; inflammatory myositis (polymyositis and dermatomyositis); systemic lupus erythematosus; systemic sclerosis (scleroderma); Sjogren's syndrome; antiphospholipid syndrome; granulomatosis with polyangiitis (Wegener's); and eosinophilic granulomatosis with polyangiitis (Churg-Strauss).

Science Team conducted a search to update the results of the previous literature review for all of the types of autoimmune diseases identified in the 2015 Webber et al. study, and also conducted a separate search for published, peer-reviewed studies of multiple sclerosis in 9/11 populations.¹⁴

The Science Team identified five additional references to review for relevance. Of the five additional references, only one study, published in 2016 by Webber et al.,¹⁵ was found to be a relevant, published, peer-reviewed study of autoimmune diseases in 9/11-exposed populations. No published, peer-reviewed epidemiologic studies of multiple sclerosis in 9/11-exposed populations were identified in the literature search.

The 2016 Webber et al. study is a follow-up to the 2015 Webber et al. study discussed above. The 2016 Webber et al. study looked at the same cohort of FDNY rescue/recovery workers included in the 2015 study to estimate the incidence of systemic autoimmune diseases in the cohort of FDNY rescue/recovery workers and to compare the FDNY incidence rates to demographically similar men and

¹⁴ Databases searched include: CINAHL, Embase, NIOSHTIC-2, PsycINFO, PubMed, Scopus, Toxicology Abstracts, and TOXLINE.

¹⁵ Mayris Webber, William Moir, Cynthia Crowson, et al., Post-September 11, 2001, Incidence of Systemic Autoimmune Diseases in World Trade Center-Exposed Firefighters and Emergency Medical Service Workers, Mayo Clin Proc 2016;91(1):23-32.

other published rates. This additional reference, the 2016 Webber et al. study, was also identified as relevant in the literature search for Petition 011. As a result, it was further reviewed in the April 2016 FRN for Petition 011 and, along with the 2015 Webber et al. study, evaluated for quantity and quality to provide a sufficient basis for deciding whether to propose an addition to the List. Significant limitations, discussed in the April 2016 FRN for Petition 011, led the WTC Health Program to conclude that the 2015 Webber et al., and the 2016 Webber et al. study together do not have the potential to provide a basis for a decision on whether to propose adding autoimmune diseases to the List.

All of the references and potential medical bases presented in Petition 013 were previously identified and assessed in Petition 011; as discussed above, these medical bases had significant limitations that prevented them from having the potential to provide a basis to propose adding autoimmune diseases to the List. The Science Team did not find any information during their review of Petition 013 which would alter the assessment of the previously reviewed studies. Moreover, none of the studies identified, including the 2015 and 2016 Webber et al. studies, include

multiple sclerosis. Thus, no evidence was found specific to multiple sclerosis which would have the potential to form the basis for a decision on whether to propose adding multiple sclerosis to the List.

D. Administrator's Determination on Petition 013

The Administrator has established a policy for evaluating whether to propose the addition of non-cancer health conditions to the List of WTC-Related Health Conditions.¹⁶ Petition 013 requested the addition of "relapsing remitting multiple sclerosis (autoimmune)" to the List. The Administrator previously reviewed the category of "autoimmune diseases," which includes multiple sclerosis, for Petitions 007, 008, 009, and 011. Neither the references included in Petition 013 nor the studies found in the literature review conducted by the Science Team presented evidence of a causal association between 9/11 exposures and autoimmune diseases, including multiple sclerosis.

The Administrator initially reviewed the findings presented in the 2015 Webber et al. study in response to

¹⁶ Supra note 6.

Petition 007, which also requested the addition of autoimmune diseases, including rheumatoid arthritis and connective tissue diseases. In that review, due to limitations in the 2015 Webber et al. study, the Administrator determined that insufficient evidence existed to take any of the following actions: propose the addition of autoimmune diseases to the List (pursuant to PHS Act, sec. 3312(a)(6)(B)(ii) and 42 CFR 88.17(a)(2)(ii)); publish a determination not to publish a proposed rule in the **Federal Register** (pursuant to PHS Act, sec. 3312(a)(6)(B)(iii) and 42 CFR 88.17(a)(2)(iii)); or request a recommendation from the STAC (pursuant to PHS Act, sec. 3312(a)(6)(B)(i) and 42 CFR 88.17(a)(2)(i)). The 2015 Webber et al. study was also presented as evidence to support the Petition 008 request for autoimmune disorders, specifically encephalitis of the brain, the Petition 009 request for autoimmune disorders, including multiple sclerosis, as well as the Petition 011 request for autoimmune disorders, including lupus and rheumatoid arthritis. The 2016 Webber et al. study was also presented as evidence to support Petition 011. As concluded in the April 2016 FRN for Petition 011, the two Webber et al. studies, taken together, while meeting the relevance

threshold of being published, peer-reviewed epidemiologic studies of autoimmune diseases in 9/11-exposed populations, were found to exhibit significant limitations and were thus insufficient to provide a potential basis for a decision on whether to propose adding the requested health conditions to the List.¹⁷

Finding no additional relevant studies with regard to Petition 013, the Administrator has accordingly determined that insufficient evidence exists to take further action at this time, including either proposing the addition of autoimmune diseases, including multiple sclerosis, to the List (pursuant to PHS Act, sec. 3312(a)(6)(B)(ii) and 42 CFR 88.17(a)(2)(ii)) or publishing a determination not to publish a proposed rule in the Federal Register (pursuant to PHS Act, sec. 3312(a)(6)(B)(iii) and 42 CFR 88.17(a)(2)(iii)). The Administrator has also determined that requesting a recommendation from the STAC (pursuant to PHS Act, sec. 3312(a)(6)(B)(i) and 42 CFR 88.17(a)(2)(i)) is unwarranted.

For the reasons discussed above, the request made in Petition 013 to add "relapsing remitting multiple sclerosis

¹⁷ 81 FR 24047 at 24050.

(autoimmune)" to the List of WTC-Related Health Conditions is denied.

The Administrator will continue to monitor the scientific literature for publication of the results of the ongoing WTC Health Registry study discussed above (reference 5 in the petition) and any other studies that address autoimmune diseases among 9/11-exposed populations.

John Howard,

Administrator, World Trade Center Health Program and
Director, National Institute for Occupational Safety and
Health, Centers for Disease Control and Prevention,
Department of Health and Human Services.

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